UNITED STATES PATENT AND TRADEMARK OFFICE

BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	Starnes
Appl. Serial No.:	10/735,094
Filed:	12/11/2003
For:	Lancet
Art Unit:	3734
Examiner:	Truong

APPEAL BRIEF

(1) Real Parties in Interest:

The real party in interest is Caribbean Medical Brokers, Inc., the assignee of record, as recorded in the records of the Patent Office at reel/frame 014993/0854.

(2) Related Appeals and Interferences:

None known to Appellant.

(3) Status of Claims:

Claims 1-3, 5-11, 12-15 and 17-22 are rejected.

Claims 4, 12 and 16 are cancelled.

(4) Status of Amendments:

There are no unentered amendments filed subsequent to the final rejection.

(5) Summary of Claimed Subject Matter:

There are four independent claims involved in this appeal - claims 1, 5, 11 and 18.

Claim 1:

Independent claim 1 defines a lancet 10 comprising:

a lancet body 20 having a distal end 24 and a needle piercing tip 32 projecting therefrom (*page 5, lines 20-23; figs. 1, 3-6*);

a cap 40 comprising an opening sized for mating engagement with the lancet distal end 24 (*page 7, lines 3-9; figs. 4-7*), where in a pre-use configuration the cap 40 is connected to the distal end 24 of the lancet body 20 by a frangible junction 50 (*page 6, lines 1-4; figs. 1-3, 3A*);

the cap 40 further comprising an interior axially projecting post 46 disposed within the opening of the cap 40 (*page 6, lines 12-14; figs. 1, 3, 5, 6*), whereby the needle piercing tip 32 is embedded within the interior axially projecting post 46 in the pre-use configuration (*page 6, lines 12-16; figs. 1-3*);

the cap 40 having at least one tab member 42 projecting therefrom (*page 6, lines 18-20; figs. 1, 4-7*);

wherein in a post-use configuration the frangible junction 50 is broken (*page 7, lines 20-23; figs. 4, 5*) and the cap 40 is mounted onto the lancet body 20 with the opening of the cap 40 receiving the lancet distal end 24 (*page 7, lines 3-9; figs. 5-7*) and with at least a portion of the piercing tip 32 embedded within the interior axially projecting post 46 (*page 7, lines 14-16; fig. 6*).

Claim 5:

Independent claim 5 defines a lancet 10 comprising:

a lancet body 20 having a distal end 24 and a piercing tip 32 projecting therefrom (*page 5, lines 20-23; figs. 1, 3-6*);

a cap 40 connected to the lancet distal end 24 by a frangible junction 50 with the piercing tip 32 embedded therein (*page 6, lines 1-4; figs. 1-3, 3A*), the cap 40 comprising an opening facing in the distal direction away from the lancet body 20 (*page 6, lines 5-16; figs 1-3*), the cap 40 being separable from the lancet body 20 at the frangible junction 50 such that the piercing tip 32 becomes exposed (*page 6, lines 1-4; page 7, lines 20-23; figs. 4, 5*);

whereby upon separation of the cap 40 from the lancet body 20 the cap 40 is postionable upon the lancet distal end 24 such that the opening receives the distal end 24 (*page 7, lines 14-16; figs. 5-7*) and the piercing tip 32 is embedded in the cap 40 (*page 7, lines 14-16; fig. 6*).

Claim 11:

Independent claim 11 defines a lancet 10 comprising:

an elongated lancet body 20 having a distal end 24 (*page 5, lines 20-21; figs. 1-7*);

a shaft 30 disposed within the lancet body 20 and comprising a piercing tip 32 projecting from the lancet distal end 24 (*page 5, lines 21-23; figs. 1, 3-6*); and

a removable cap 40 having a first position connected to the lancet distal end 24 by a frangible junction 50 with the piercing tip 32 embedded within the frangible junction 50 (*page 6, lines 1-4; figs. 1-3, 3A*), the cap 40 comprising a generally cylindrical opening coaxially aligned with the shaft 30 and facing in the distal direction away from the lancet body 20 (*page 6, lines 5-16; figs 1-3*);

the cap 40 being removable from the lancet body 20 by destruction of the frangible junction 50 (*page 7, lines 20-23; figs. 4, 5*),

whereby the cap 40 has a second position such that the opening of the cap 40 is facing toward the lancet body 20 such that the distal end 24 of the lancet body 20 is received by the opening (*page 7, lines 14-16; figs. 5-7*) and the piercing tip 32 is embedded in the cap 40 (*page 7, lines 14-16; fig. 6*).

Claim 18:

Independent claim 18 defines a lancet 10 comprising:

an elongated lancet body 20 having a distal end 24 (*page 5, lines 20-21; figs. 1-7*);

a shaft 30 disposed within the lancet body 20 and comprising a piercing tip 32 projecting from the distal end 24 of the lancet body 20 (*page 5, lines 21-23; figs. 1, 3-6*);

a removable cap 40 connected to the lancet distal end 24 by a frangible junction 50 with the piercing tip 32 embedded therein (*page 6, lines 1-4; figs. 1-3, 3A*), the cap 40 comprising a generally cylindrical opening, the cap 40 being generally cylindrical and coaxially aligned with the shaft 30 prior to separation of the frangible junction 50 and removal of the cap 40 from the lancet body 20 (*page 6, lines 5-16; figs 1-4*); and

at least one tab member 42 projecting radially from the cap member 40 (*page 6, lines 18-20; figs. 1, 4-7*).

In table format for ease of review, the four independent claims with reference to the specification and drawings read verbatim as follows:

1. A lancet 10 having	
a pre-use and	*Page 6, lines 5-16; Figs. 1-3.*
a post-use configuration,	*Page 7, lines 3-19; Figs. 6, 7.*
said lancet 10 comprising:	
a lancet body 20 having a distal end 24 and a needle piercing tip 32 projecting from said distal end 24;	*Page 5, lines 20-23; Figs. 1, 3-6.*
a cap 40,	*Page 5, lines 24-25; Figs. 1-7.*
said cap 40 in a pre-use configuration connected to said distal end 24 by a frangible junction 50,	*Page 6, lines 1-4; Figs. 1-3, 3A.*
said cap 40 comprising an opening sized for mating engagement with said lancet distal end 24;	*Page 7, lines 3-9; Figs. 4-7.*
an interior axially projecting post 46 disposed within said opening of said cap 40,	*Page 6, lines 12-14; Figs. 1, 3, 5, 6.*
whereby said needle piercing tip 32 is embedded within said interior axially projecting post 46 in said pre-use configuration;	*Page 6, lines 12-16; Figs. 1-3.*

said cap 40 having at least one tab member 42 projecting therefrom;	*Page 6, lines 18-20; Figs. 1, 4-7.*
wherein in a post-use configuration said frangible junction 50 is broken	*Page 7, lines 20-23; Figs. 4, 5.*
and said cap 40 is mounted onto said lancet body 20 with said opening of said cap 40 receiving said lancet distal end 24	*Page 7, lines 3-9; Figs. 5-7.*
and at least a portion of said piercing tip 32 embedded within said interior axially projecting post 46.	*Page 7, lines 14-16; Fig. 6.*
5. A lancet 10 comprising:	
a lancet body 20 having a distal end 24 and a piercing tip 32 projecting from said distal end 24;	*Page 5, lines 20-23; Figs. 1, 3-6.*
a cap 40	*Page 5, lines 24-25: Figs. 1-7.*
connected to said distal end 24 with said piercing tip 32 embedded therein by a frangible junction 50,	*Page 6, lines 1-4; Figs. 1-3, 3A.*
said cap 40 comprising an opening facing in the distal direction away from said lancet body 20,	*Page 6, lines 5-16; Figs 1-3.*

said cap 40 separable from said lancet body 20 at said frangible junction 50 such that said piercing tip 32 is exposed;	*Page 6, lines 1-4; Page 7, lines 20-23; Figs. 4, 5.*
whereby upon separation of said cap 40 from said lancet body 20 said cap 40 is postionable upon said distal end 24 of said lancet body 20 such that said opening receives said distal end 24	*Page 7, lines 14-16; Figs. 5-7.*
and said piercing tip 32 is embedded in said cap 40.	*Page 7, lines 14-16; Fig. 6.*
11. A lancet 10 comprising:	
an elongated lancet body 20 having a distal end 24;	*Page 5, lines 20-21; Figs. 1-7.*
a shaft 30 disposed within said lancet body 20, said shaft 30 comprising a piercing tip 32 projecting from said distal end 24 of said lancet body 20; and	*Page 5, lines 21-23; Figs. 1, 3-6.*
a removable cap 40 having a first position connected to said distal end 24 of said lancet body 20 by a frangible junction 50 with said piercing tip 32 embedded within said	*Page 6, lines 1-4; Figs. 1-3, 3A.*

frangible junction 50,	
said cap 40 comprising a generally cylindrical opening coaxially aligned with said shaft 30 and facing in the distal direction away from said lancet body 20;	*Page 6, lines 5-16; Figs 1-3.*
said cap 40 being removable from said lancet body 20 by destruction of said frangible junction 50,	*Page 7, lines 20-23; Figs. 4, 5.*
whereby said cap 40 has a second position such that said opening of said cap 40 is facing toward said lancet body 20 such that said distal end 24 of said lancet body 20 is received by said opening	*Page 7, lines 14-16; Figs. 5-7.*
and said piercing tip 32 is embedded in said cap 40.	*Page 7, lines 14-16; Fig. 6.*
18. A lancet 10 comprising:	
an elongated lancet body 20 having a distal end 24;	*Page 5, lines 20-21; Figs. 1-7.*
a shaft 30 disposed within said lancet body 20, said shaft 30 comprising a piercing tip 32 projecting from said distal end 24 of said	*Page 5, lines 21-23; Figs. 1, 3-6.*

lancet body 20:	
a removable cap 40	*Page 5, lines 24-25: Figs. 1-7.*
connected to said distal end 24 of said lancet body 20 by a frangible junction 50 with said piercing tip 32 embedded therein,	*Page 6, lines 1-4; Figs. 1-3, 3A.*
said cap 40 comprising a generally cylindrical opening, said cap 40 being generally cylindrical and coaxially aligned with said shaft 30 prior to separation of said frangible junction 50 and removal of said cap 40 from said lancet body 20; and	*Page 6, lines 5-16; Figs 1-4.*
at least one tab member 42 projecting radially from said cap member 40.	*Page 6, lines 18-20; Figs. 1, 4-7.*

(6) Grounds of Rejection to be Reviewed on Appeal:

I. Whether Claims 1-3, 5-11, 12-15 and 17-22 are unpatentable under 35 U.S.C. 102(b) as being anticipated by Morita (US 5,385,571).

(7) **Argument:**

Rejection under 35 U.S.C. 102(b) over Morita (US 5,385,571).

The Examiner has rejected the claims under Section 102(a) as anticipated by Morita '571. As previously argued in the Amendment and Response filed 06/20/2006, in the Amendment and Response filed with the RCE Request on 02/14/2007, and in the Response After Final Rejection filed 05/03/2007, it is submitted that Morita does not meet the minimum requirements for maintaining a rejection based on anticipation, as all of the essential elements set forth in the claim are not identically set forth in Morita. *Herman v. William Brooks Shoe Co.*, 54 USPQ2d 1046 (S.D. N.Y. 2000); *Gechter v. Davidson*, 116 F.3rd 1454, 1457, 43 USPQ2d, 1030, 1032 (Fed. Cir. 1997). As set forth in MPEP Sect. 2131, a claim is anticipated under 35 U.S.C. 102 "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

In the case of each independent claim, elements set forth in the claims are not expressly or inherently described or found in Morita.

Claims 1 through 3:

Independent claim 1 requires in part (reference numbers and emphasis added) "an interior axially projecting post 46 disposed within said opening of said cap 40, whereby said needle piercing tip 32 is embedded within said interior axially projecting post 46 in said pre-use configuration" (Fig. 1) and further requires that "in a post-use configuration ... said cap 40 is mounted onto said lancet body 20 with said opening of said cap 40 receiving said lancet distal end 24 and at least a portion of said piercing tip 32 embedded within said axially projecting post 46" (Fig. 6).

Morita lacks an interior axially projecting post disposed within the opening of the cap. Instead, Morita discloses an elongated bore 38 or recess 42 positioned axially within the needle protector 14 (Figs. 10 and 12).

The piercing tip 16 of Morita is not embedded within a post member in the pre-use configuration, as there is no post structure in Morita, but is instead disposed within the body of the cap itself (Figs. 7, 11) or within a flange member that is not an interior axially projecting post (Figs. 3).

In the post-use configuration with the cover 14 mounted onto the lancet body, the piercing tip 16 of Morita is either embedded within the body of the protective cover itself (Fig. 2 prior art and Fig. 6), extends into a bore 38 that passes completely through the cover 14 (Fig. 10), or extends into the recess 42 (Fig. 12).

The structure of Morita is the exact opposite in function and structure of that of claim 1, in that the recess 42 produces a lesser material thickness to receive the needle, whereas the post 46 of the claim produces a greater material thickness. The presence of the post 46 allows the

piercing tip to be fully embedded in both the pre-use and post-use configuration with only a small amount of additional material, as opposed to making the entire bottom of the cap 40 thick (as seen in Morita Fig. 6). Likewise, an extended flange member or thick cap sides are not required, as opposed to the Morita designs (Fig. 3, 7), again saving material. Less material results in cost savings in manufacture. Additionally, the presence of the axially projecting post 46 acts to better secure the cap 40 on the piercing tip 32 in both the pre-use and, most importantly, post-use configurations (after the needle has been contaminated).

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 1, it does not anticipate claim 1, and rejection of claims 1 through 3 under Section 102 over Morita is improper.

Claims 5 and 7:

Independent claim 5 requires in part (reference numbers and emphasis added) "a cap 40 connected to said distal end 24 with said piercing tip 32 embedded therein by a frangible junction 50, said cap 40 comprising an opening facing in the distal direction away from said lancet body 20 (Figs. 1-3), said cap 40 separable from said lancet body at said frangible junction such that said piercing tip is exposed" (Fig. 4).

Morita fails to disclose structure or elements meeting the limiting language of the claims. As illustrated in Figures 3, 4, 7, 8 and 11 of Morita, when the piercing tip 16 is embedded in the cap 14, the opening 28 does not face in the distal direction away from the lancet body. Instead the opening 28 faces in the lateral or radial direction transverse to the proximal-distal direction

axis. Because of this structure, the wall thickness of the Morita device must be increased in order to receive the piercing tip 16 in the pre-use configuration (Figs. 7, 11), or a separate extension flange must be provided (Fig. 3). This added material increases manufacturing costs.

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 5, it does not anticipate claim 5, and rejection of claims 5 and 7 under Section 102 over Morita is improper.

Claim 6:

Claim 6, dependent on independent claim 5, requires in part (reference numbers and emphasis added) cap 40 to comprise "first and second diametrically opposed radially projecting tabs 42" (Figs. 1, 4-7).

Morita shows no embodiment with plural opposed tabs. Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 6, it does not anticipate claim 6, and rejection of claim 6 under Section 102 over Morita is improper.

Claim 8:

Claim 8, dependent on independent claim 5, requires in part (reference numbers and emphasis added) cap 40 to comprise "an interior axially projecting post 46 within said opening for receiving at least a portion of said piercing tip 32 embedded therein both when said cap 40 is

connected to said distal end 24 (Fig. 1) and when said cap 40 is positioned with said distal end 24 received by said opening" (Fig. 6).

Morita lacks an interior axially projecting post disposed within the opening of the cap. Instead, Morita discloses an elongated bore 38 or recess 42 positioned axially within the needle protector 14 (Figs. 10 and 12).

The piercing tip 16 of Morita is not embedded within a post member when the cap is connected to the lancet distal end, as there is no post structure in Morita, but is instead disposed within the body of the cap itself (Figs. 7, 11) or within a flange member that is not an interior axially projecting post (Figs. 3).

In the post-use configuration with the cover 14 positioned receiving the lancet distal end, the piercing tip 16 of Morita is either embedded within the body of the protective cover itself (Fig. 2 prior art and Fig. 6), extends into a bore 38 that passes completely through the cover 14 (Fig. 10), or extends into the recess 42 (Fig. 12).

The structure of Morita is the exact opposite in function and structure of that of claim 1, in that the recess 42 produces a lesser material thickness to receive the needle, whereas the post 46 of the claim produces a greater material thickness. The presence of the post 46 allows the piercing tip to be fully embedded in both the pre-use and post-use configuration with only a small amount of additional material, as opposed to making the entire bottom of the cap 40 thick (as seen in Morita Fig. 6). Likewise, an extended flange member or thick cap sides are not required, as opposed to the Morita designs (Fig. 3, 7), again saving material. Less material results in cost savings in manufacture. Additionally, the presence of the axially projecting post 46 acts to better secure the cap 40 on the piercing tip 32 in both the pre-use and, most importantly, post-use configurations (after the needle has been contaminated).

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 8, it does not anticipate claim 8, and rejection of claim 8 under Section 102 over Morita is improper.

Claims 9 and 10:

Claim 9, dependent on claim 8, requires in part (reference numbers and emphasis added) cap 40 to comprise "first and second diametrically opposed radially projecting tabs 42" (Figs. 1, 4-7).

Morita shows no embodiment with plural opposed tabs. Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 9, it does not anticipate claim 9, and rejection of claims 9 and 10 under Section 102 over Morita is improper.

Claims 11 and 13:

Independent claim 11 requires in part (reference numbers and emphasis added) "a shaft 30 disposed within said lancet body 20, ...a removable cap 40 having a first position connected to said distal end 24 of said lancet body 20 by a frangible junction 50, ... said cap 40 comprising a generally cylindrical opening coaxially aligned with said shaft and facing in the distal direction away from said lancet body 20" (Figs. 1-3).

Morita fails to disclose structure or elements meeting the limiting language of the claims. As illustrated in Figures 3, 4, 7, 8 and 11 of Morita, when the piercing tip 16 is embedded in the cap 14, the opening 28 does not face in the distal direction away from the lancet body. Instead the opening 28 faces in the lateral or radial direction transverse to the proximal-distal direction axis. Because of this structure, the wall thickness of the Morita device must be increased in order to receive the piercing tip 16 in the pre-use configuration (Figs. 7, 11), or a separate extension flange must be provided (Fig. 3). This added material increases manufacturing costs.

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 11, it does not anticipate claim 11, and rejection of claims 11 and 13 under Section 102 over Morita is improper.

Claim 14:

Claim 14, dependent on independent claim 11, requires in part (reference numbers and emphasis added) cap 40 to comprise "first and second diametrically opposed radially projecting tabs 42" (Figs. 1, 4-7).

Morita shows no embodiment with plural opposed tabs. Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 14, it does not anticipate claim 14, and rejection of claim 14 under Section 102 over Morita is improper.

Claim 15:

Claim 15, dependent on independent claim 11, requires in part (reference numbers and emphasis added) cap 40 to comprise "an interior axially projecting post 46 disposed within said opening for receiving at least a portion of said piercing tip 32 embedded therein when said cap 40 is in either said first (Fig. 1) or said second position" (Fig. 6).

Morita lacks an interior axially projecting post disposed within the opening of the cap. Instead, Morita discloses an elongated bore 38 or recess 42 positioned axially within the needle protector 14 (Figs. 10 and 12).

The piercing tip 16 of Morita is not embedded within a post member in the first position, as there is no post structure in Morita, but is instead disposed within the body of the cap itself (Figs. 7, 11) or within a flange member that is not an interior axially projecting post (Figs. 3).

In the second position with the cover 14 mounted onto the lancet body, the piercing tip 16 of Morita is either embedded within the body of the protective cover itself (Fig. 2 prior art and Fig. 6), extends into a bore 38 that passes completely through the cover 14 (Fig. 10), or extends into the recess 42 (Fig. 12).

The structure of Morita is the exact opposite in function and structure of that of claim 1, in that the recess 42 produces a lesser material thickness to receive the needle, whereas the post 46 of the claim produces a greater material thickness. The presence of the post 46 allows the piercing tip to be fully embedded in both the pre-use and post-use configuration with only a small amount of additional material, as opposed to making the entire bottom of the cap 40 thick (as seen in Morita Fig. 6). Likewise, an extended flange member or thick cap sides are not required, as opposed to the Morita designs (Fig. 3, 7), again saving material. Less material

results in cost savings in manufacture. Additionally, the presence of the axially projecting post 46 acts to better secure the cap 40 on the piercing tip 32 in both the first and, most importantly, second positions (after the needle has been contaminated).

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 15, it does not anticipate claim 15, and rejection of claim 15 under Section 102 over Morita is improper.

Claim 17:

Claim 17, dependent on independent claim 14, requires in part (reference numbers and emphasis added) cap 40 to comprise "an interior axially projecting post 46 disposed within said opening for receiving at least a portion of said piercing tip 32 embedded therein when said cap 40 is in either said first (Fig. 1) or said second position" (Fig. 6).

Morita lacks an interior axially projecting post disposed within the opening of the cap. Instead, Morita discloses an elongated bore 38 or recess 42 positioned axially within the needle protector 14 (Figs. 10 and 12).

The piercing tip 16 of Morita is not embedded within a post member in the first position, as there is no post structure in Morita, but is instead disposed within the body of the cap itself (Figs. 7, 11) or within a flange member that is not an interior axially projecting post (Figs. 3).

In the second position with the cover 14 mounted onto the lancet body, the piercing tip 16 of Morita is either embedded within the body of the protective cover itself (Fig. 2 prior art

and Fig. 6), extends into a bore 38 that passes completely through the cover 14 (Fig. 10), or extends into the recess 42 (Fig. 12).

The structure of Morita is the exact opposite in function and structure of that of claim 1, in that the recess 42 produces a lesser material thickness to receive the needle, whereas the post 46 of the claim produces a greater material thickness. The presence of the post 46 allows the piercing tip to be fully embedded in both the pre-use and post-use configuration with only a small amount of additional material, as opposed to making the entire bottom of the cap 40 thick (as seen in Morita Fig. 6). Likewise, an extended flange member or thick cap sides are not required, as opposed to the Morita designs (Fig. 3, 7), again saving material. Less material results in cost savings in manufacture. Additionally, the presence of the axially projecting post 46 acts to better secure the cap 40 on the piercing tip 32 in both the first and, most importantly, second positions (after the needle has been contaminated).

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 17, it does not anticipate claim 17, and rejection of claim 17 under Section 102 over Morita is improper.

Claims 18 and 20:

Independent claim 18 requires in part (reference numbers and emphasis added) "a shaft 30 disposed within said lancet body 20, ...a removable cap 40 connected to said distal end 24 of said lancet body 20 by a frangible junction 50, ... said cap 40 comprising a generally cylindrical

opening, said cap ... coaxially aligned with said cap aligned with said shaft prior to separation of said frangible junction" (Figs. 1-3).

Morita fails to disclose structure or elements meeting the limiting language of the claims. As illustrated in Figures 3, 4, 7, 8 and 11 of Morita, when the piercing tip 16 is embedded in the cap 14, the opening 28 is not coaxially aligned with the shaft. Instead the opening 28 faces in the lateral or radial direction transverse to the proximal-distal direction axis. Because of this structure, the wall thickness of the Morita device must be increased in order to receive the piercing tip 16 in the pre-use configuration (Figs. 7, 11), or a separate extension flange must be provided (Fig. 3). This added material increases manufacturing costs.

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 18, it does not anticipate claim 18, and rejection of claims 18 and 20 under Section 102 over Morita is improper.

Claim 19:

Claim 19, dependent on independent claim 18, requires in part (reference numbers and emphasis added) cap 40 to comprise "first and second diametrically opposed radially projecting tabs 42" (Figs. 1, 4-7).

Morita shows no embodiment with plural opposed tabs. Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 14, it does not anticipate claim 14, and rejection of claim 14 under Section 102 over Morita is improper.

Claims 21 and 22:

Claim 21, dependent on independent claim 20, requires in part (reference numbers and emphasis added) cap 40 to comprise "an interior axially projecting post 46 disposed within said opening receiving at least a portion of said piercing tip 32 embedded therein when said cap 40 is removed from said lancet body 20, reversed and said opening is matingly engaged with said lancet distal end 24" (Fig. 6).

Morita lacks an interior axially projecting post disposed within the opening of the cap. Instead, Morita discloses an elongated bore 38 or recess 42 positioned axially within the needle protector 14 (Figs. 10 and 12).

With the cover 14 mounted onto the lancet body, the piercing tip 16 of Morita is either embedded within the body of the protective cover itself (Fig. 2 prior art and Fig. 6), extends into a bore 38 that passes completely through the cover 14 (Fig. 10), or extends into the recess 42 (Fig. 12).

The structure of Morita is the exact opposite in function and structure of that of claim 1, in that the recess 42 produces a lesser material thickness to receive the needle, whereas the post 46 of the claim produces a greater material thickness. The presence of the post 46 allows the piercing tip to be fully embedded in both the pre-use and post-use configuration with only a small amount of additional material, as opposed to making the entire bottom of the cap 40 thick (as seen in Morita Fig. 6). Likewise, an extended flange member or thick cap sides are not required, as opposed to the Morita designs (Fig. 3, 7), again saving material. Less material results in cost savings in manufacture. Additionally, the presence of the axially projecting post

46 acts to better secure the cap 40 on the piercing tip 32 in both the first and, most importantly, second positions (after the needle has been contaminated).

Because Morita fails to disclose, either expressly or inherently, elements set forth in claim 21, it does not anticipate claim 21, and rejection of claims 21 and 22 under Section 102 over Morita is improper.

For the reasons set forth above, it is respectfully requested that the final rejection of the claims at issue be reversed in whole, and that the claims be passed for allowance and issue.

Respectfully submitted,

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The undersigned certifies that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.

10/10/07
Date

Thomas C. Saitta

Claims Appendix:

1. A lancet having a pre-use and a post-use configuration, said lancet comprising:

a lancet body having a distal end and a needle piercing tip projecting from said distal end;

a cap, said cap in a pre-use configuration connected to said distal end by a frangible junction, said cap comprising an opening sized for mating engagement with said lancet distal end;

an interior axially projecting post disposed within said opening of said cap, whereby said needle piercing tip is embedded within said interior axially projecting post in said pre-use configuration;

said cap having at least one tab member projecting therefrom;

wherein in a post-use configuration said frangible junction is broken and said cap is mounted onto said lancet body with said opening of said cap receiving said lancet distal end and at least a portion of said piercing tip embedded within said interior axially projecting post.

2. A lancet according to claim 1, wherein said cap is generally cylindrical and includes first and second diametrically opposed radially projecting tabs.

3. A lancet according to claim 1, wherein said cap defines an opening sized for mating engagement with said lancet distal end and an interior shoulder providing a stop upon engagement with said lancet distal end.

4. (canceled)

5. A lancet comprising:

a lancet body having a distal end and a piercing tip projecting from said distal end;

a cap connected to said distal end with said piercing tip embedded therein by a frangible junction, said cap comprising an opening facing in the distal direction away from said lancet body, said cap separable from said lancet body at said frangible junction such that said piercing tip is exposed;

whereby upon separation of said cap from said lancet body said cap is postionable upon said distal end of said lancet body such that said opening receives said distal end and said piercing tip is embedded in said cap.

6. The lancet of claim 5, wherein said cap is generally cylindrical and further comprises first and second diametrically opposed radially projecting tabs.

7. The lancet of claim 6, wherein said cap further comprises an interior shoulder providing a stop upon engagement with said lancet distal end.

8. The lancet of claim 5, wherein said cap further comprises an interior axially projecting post disposed within said opening for receiving at least a portion of said piercing tip embedded therein both when said cap is connected to said distal end and when said cap is positioned with said distal end received by said opening.

9. The lancet of claim 8, wherein said cap is generally cylindrical and further comprises first and second diametrically opposed radially projecting tabs.

10. The lancet of claim 9, wherein said cap further comprises an interior shoulder providing a stop upon engagement with said lancet distal end.

11. A lancet comprising:

an elongated lancet body having a distal end;

a shaft disposed within said lancet body, said shaft comprising a piercing tip projecting from said distal end of said lancet body; and

a removable cap having a first position connected to said distal end of said lancet body by a frangible junction with said piercing tip embedded within said frangible junction, said cap comprising a generally cylindrical opening coaxially aligned with said shaft and facing in the distal direction away from said lancet body;

said cap being removable from said lancet body by destruction of said frangible junction, whereby said cap has a second position such that said opening of said cap is facing toward said lancet body such that said distal end of said lancet body is received by said opening and said piercing tip is embedded in said cap.

12. (canceled)

13. The lancet of claim 11, wherein said cap further comprises at least one tab member projecting therefrom.

14. The lancet of claim 11, wherein said cap further comprises first and second diametrically opposed radially projecting tabs.

15. The lancet of claim 11, wherein said cap further comprises an interior axially projecting post disposed within said opening for receiving at least a portion of said piercing tip embedded therein when said cap is in either said first or said second position.

16. (canceled)

17. The lancet of claim 14, wherein said cap further comprises an interior axially projecting post disposed within said opening for receiving at least a portion of said piercing tip embedded therein when said cap is in either said first or said second position.

18. A lancet comprising:

an elongated lancet body having a distal end;

a shaft disposed within said lancet body, said shaft comprising a piercing tip projecting from said distal end of said lancet body;

a removable cap connected to said distal end of said lancet body by a frangible junction with said piercing tip embedded therein, said cap comprising a generally cylindrical opening, said cap being generally cylindrical and coaxially aligned with said shaft prior to separation of said frangible junction and removal of said cap from said lancet body; and

at least one tab member projecting radially from said cap member.

19. The lancet of claim 18, said at least one tab member comprising first and second diametrically opposed radially projecting tabs.

20. The lancet of claim 19, said opening being coaxially aligned with said shaft prior to separation of said frangible junction and removal of said cap from said lancet body.

21. The lancet of claim 20, wherein said cap further comprises an interior axially projecting post disposed within said opening receiving at least a portion of said piercing tip embedded therein when said cap is removed from said lancet body, reversed and said opening is matingly engaged with said lancet distal end.

22. The lancet of claim 21, wherein said cap further comprises an interior shoulder providing a stop upon engagement with said lancet distal end.

(9) Evidence Appendix

None.

(10) Related Proceedings Appendix

None.